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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yiqun Wang

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/784,665	<b>Applicant(s)</b> WANG ET AL.	
	<b>Examiner</b> KATHERINE M. DOWE	<b>Art Unit</b> 3734	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22,24-26,28 and 30-37 is/are pending in the application.
- 4a) Of the above claim(s) 31-34 and 36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22,24-26,28,30,35 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 19, 2010 has been entered.
2. Claims 22, 24-26, 28, 30, 35, and 37 are currently pending. Claims 31-34 and 36 have been withdrawn from consideration.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:  

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
4. Claims 22, 24-26, 28, 30, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the originally filed disclosure for the limitation of the seal member having a solid cross-section, as recited in claim 22. There is support that the seal is a solid member (specification page 12, lines 3-8), however the member must be punctured or penetrated with a penetrating member such as a needle to deliver inflation fluid or pull a vacuum (specification page 12, lines 9-16). Although the seal self-seals such that it remains substantially resistant to the passage of air or fluids after a selected penetrating member is removed from the seal, there is insufficient support that at least a

minimal hole or opening does not remain from the path of the penetrating member such that the seal may have a "solid" cross-section. For the purpose of examination, the "solid cross-section" is interpreted as including the minimal hole or opening created from a puncture member or the cross-section of the seal prior to being punctured by a puncturing member.

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 22, 24-26, 28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto et al. (US 4,610,665, hereinafter "Matsumoto") in view of Picha et al. (US 5,080,654, hereinafter "Picha") and Rauker et al. (US 6,475,185, hereinafter "Rauker").

Matsumoto discloses the invention substantially as claimed including a catheter (70), comprising: an elongate catheter shaft (71) having a proximal end, a distal end, a guidewire lumen (72) defined therethrough, and an inflation lumen (75) defined therethrough; a balloon (74) disposed adjacent the distal end of the catheter shaft, the balloon being in fluid communication with the inflation lumen; a port (76) disposed at the proximal end of the catheter shaft, the port having an opening defined therein that is in fluid communication with the inflation lumen, and a self-sealing seal member (16) attached to the end of the port and covering the opening (Fig. 16 and 17). The seal (16) is pierceable, is generally planar, and may extend laterally beyond the flanged end of the port (Fig 11). A cap (78) is coupled to the port and disposed over the seal (Fig 17).

However, Matsumoto fails to disclose the seal member is releasably attached to the flanged end. Picha discloses a self-sealing seal member (20) that is releasably attached the flanged end of a port, and the flange helps to secure the elastomeric seal in place (col. 3, ln. 6-

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42). The seal is pierceable (col. 3, ln. 12 and 56-58), is generally planar at the proximal end (Fig 4), and may extend laterally beyond the flanged end (15) of the port (Fig 4). A cap (30) is coupled to the port and disposed over the seal (Fig. 5). It would have been obvious to one of ordinary skill in the art to modify the seal assembly of Matsumoto such that the seal member was releasably attached to the flanged end, since it is a well known feature as taught by Picha and it would provide the same function of maintaining a fluid-tight seal during insertion of and after removal of an injection member. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Furthermore, Matsumoto discloses the self-sealing seal member comprises slits (17/18) that form a fluid tight seal about the piercing member (77), wherein the slits have a minimal width and the seal (16) is formed of an elastomeric material such that upon removal of the piercing member (77) the slits form a perfect seal to prevent inflation fluid from flowing out of the balloon. However, Matsumoto teaches the slits (17/18) are pre-formed and thus fails to disclose the seal member has a solid cross-section. Rauker discloses a similar seal (34) disposed in a port of a balloon catheter (Fig 2), wherein the seal has a solid cross-section formed of a self-sealing material such as medical grade silicone rubber or other suitable polymeric material (col 3, ln 66 – col 4, ln 3). The seal (34) is capable of being pierced by a needle (42) to deliver fluid therethrough to a distal balloon (col 4, ll 9-14). Since the solid seal (34) is self-sealing, upon withdrawal of the needle, the seal member is capable of maintaining a vacuum with the inflation lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the invention of Matsumoto such that the pre-formed slits (17/18) were replaced with a seal member having a self-sealing solid cross-section. Such a modification would further ensure fluid cannot pass through the seal unintentionally.

7. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rauker (US 6,475,185) in view of Picha (US 5,080,654) and McClure et al. (US 5,507,732, hereinafter "McClure") and Andrews et al. ("The Comparison of Certain Commercial Getters", 1931). Rauker discloses the invention substantially as claimed including a balloon catheter (Fig 1) comprising an elongate catheter shaft (30) having a proximal end region and a proximal port (Fig 2) disposed adjacent the proximal end region. A balloon (32) is disposed adjacent the distal end and an inflation lumen extends between the port and balloon (col 3, ll 51-57). The port includes a seal (34) that seals the inflation lumen, wherein the seal does not include a pre-formed opening (col 3, ln 66 – col 4, ln 3).

However, Matsumoto fails to disclose the seal member is releasably attached to a proximal flanged end. Picha discloses a self-sealing seal member (20) that is releasably attached the flanged end of a port, and the flange helps to secure the elastomeric seal in place (col. 3, ln. 6-42). The seal is pierceable (col. 3, ln. 12 and 56-58), is generally planar at the proximal end (Fig 4), and may extend laterally beyond the flanged end (15) of the port (Fig 4). A cap (30) is coupled to the port and disposed over the seal (Fig. 5). It would have been obvious to one of ordinary skill in the art to modify the seal assembly of Rauker such that the seal member was releasably attached to a flanged end, since it is a well known feature as taught by Picha and it would provide the same function of maintaining a fluid-tight seal during insertion of and after removal of an injection member. Substitution of one known element for another element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

Furthermore, Rauker does not disclose an inner surface of the lumen includes a chemical coating capable of binding air. McClure discloses a seal arrangement (Fig 1) for use

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with a typical balloon catheter (col 1, ll 11-23). McClure teaches the purpose of the seal arrangement is to hold pressure under balloon inflation as well as vacuum under balloon deflation (col 4, ll 14-17). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rauker such that the self-sealing function of the seal member (34) prevented the passage of fluid such that it was capable of both holding pressure under balloon inflation and holding vacuum under balloon deflation. Thus, the balloon (32) will not unintentionally slightly deflate after time when it is intended to be inflated or slightly expand over time when it is intended to be completely deflated. Additionally, when referring to the chemical coating capable of binding air, Applicant states, "A person of ordinary skill in the art would be familiar with a getter and the use thereof according to multiple embodiments of the invention." (see specification as originally filed, page 11, lines 8-9). As evidenced by the article, "The Comparison of Certain Commercial Getters" (1931), it is old and well known in the art to apply a chemical coating capable of binding air to a valve/sealing system to improve the vacuum capability of the device. Therefore, it would have been prima facie obvious to try modifying the combination of Rauker, Picha, and McClure such that the an inner surface of the lumen includes a chemical coating capable of binding air in an attempt to provide an improved vacuum as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

8. Claims 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsumoto (US 4,610,665), Picha (US 5,080,654) and Rauker (US 6,475,185), as applied to claim 22 above, further in view of McClure (US 5,507,732) and Andrews et al. ("The Comparison of Certain Commercial Getters", 1931). Matsumoto, Picha, and Rauker disclose the invention

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substantially as claimed, as shown above. However, they do not disclose an inner surface of the lumen includes a chemical coating capable of binding air. McClure discloses a seal arrangement (Fig 1) for use with a typical balloon catheter (col 1, ll 11-23). McClure teaches the purpose of the seal arrangement is to hold pressure under balloon inflation as well as vacuum under balloon deflation (col 4, ll 14-17). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Matsumoto, Picha, and Rauker such that the self-sealing function of the seal member prevented the passage of fluid such that it was capable of both holding pressure under balloon inflation and holding vacuum under balloon deflation. Thus, the balloon will not unintentionally slightly deflate after time when it is intended to be inflated or slightly expand over time when it is intended to be completely deflated. Additionally, when referring to the chemical coating capable of binding air, Applicant states, "A person of ordinary skill in the art would be familiar with a getter and the use thereof according to multiple embodiments of the invention." (see specification as originally filed, page 11, lines 8-9). As evidenced by the article, "The Comparison of Certain Commercial Getters" (1931), it is old and well known in the art to apply a chemical coating capable of binding air to a valve/sealing system to improve the vacuum capability of the device. Therefore, it would have been prima facie obvious to try modifying the combination of Matsumoto, Rauker, Picha, and McClure such that the an inner surface of the lumen includes a chemical coating capable of binding air in an attempt to provide an improved vacuum as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.



***Response to Arguments***

9. Applicant's arguments with respect to claims 22, 24-26, 28, 30, and 35 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Katherine M Dowe/  
Examiner, Art Unit 3734

March 26, 2011